Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1069404	10/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
98 Point 6 Emergicenter	1540 Lake Lansing Road Suite 203, Lansing, MI	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation and interview with testing personnel #1, the laboratory failed to ensure its blood culture bottles and stool specimen collection kits had not exceeded expiration dates for 14 of 14 total blood culture and stool specimen collection kits observed in the laboratory. Findings include: 1. The surveyor observed the following expired materials during a tour of the laboratory on 10/27/25 at 8:51 am: a. Ten total BD BACTEC Blood Culture Vials with the following expiration dates: i. Two bottles with the expiration date of 8/22/25. ii. Seven bottles with the expiration date of 10/13 /25. iii. One bottle with the expiration date of 10/14/25. b. Four Zinc-PVA/Formalin /C&S O&P stool specimen collection kits with the expiration date of 6/30/25. 2. An interview on 10/27/25 at 9:02 am with testing personnel #1 confirmed the blood culture bottles and stool specimen collection kits had exceeded their expiration dates.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by:

	. Based on a lack of documentation and interviews with testing personnel #1, the laboratory failed to perform and document its weekly cleaning maintenance for the Hemocue analyzer for two (October 2023 to October 2025) of two years. Findings include: 1. The surveyor requested documentation of instrument maintenance records on 10/27/25 at 12:33 pm. 2. An interview on 10/27/25 at 10:10 am with testing personnel #1 revealed the laboratory performs weekly cleaning of the Hemocue analyzer with alcohol. 3. An interview on 10/27/25 at 12:33 pm with testing personnel #1 revealed the weekly Hemocue cleaning maintenance had not been documented.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1, the laboratory failed to perform calibration verification at least once every six months for its i-STAT Chem8+ panel for two (October 2023 to October 2025) of two years reviewed. Findings include: 1. A review of the laboratory's i-STAT instructions for use revealed a section titled "Calibration Verification" stating, "Calibration Verification, also known as a linearity check, is a procedure intended to verify the accuracy of results over the entire measurement range of a test. Because of the inherent stability of the i-STAT system, Abbott Point of Care does not make any specific recommendations for the calibration verification procedure. Therefore, it is the responsibility of the laboratory to determine when and how this procedure should be performed." 2. A review of the laboratory's "Chem8 i-STAT Device" policy revealed a lack of information for how and when the laboratory performs calibration verification. 3. An interview on 10/27/25 at 11:23 am with testing personnel #1 revealed the laboratory had not performed calibration verification for its i-STAT Chem8+ panel for the previous two years.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report

	destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: . Based on record review and interview with testing personnel #1, the laboratory failed to accurately transcribe test report data into the final test report for two (Patients #2 and #14) of 16 patient test reports reviewed. Findings include: 1. A review of 16 patient test records and cooresponding patient test reports, the following patients had discrepancies between test records and reports: a. Patient #2 had an i-STAT Chem8+ test performed on 1/20/24. Review of the instrument print out and final test report revealed a discrepancy with Patient #2's first name. The instrument print out listed a different first name when compared to the final test report. b. Patient #14 had an i-STAT Chem8+ test performed on 9/27/25. The instrument print out listed the blood glucose result as "139 mg/dL". The final report listed the blood glucose result as "130 mg/dL". 2. An interview on 10/27/25 at 12:00 pm with testing personnel #1 confirmed the reporting discrepancies listed above. ***This is a repeated deficiency from the 3/4 /22 recertification survey.***
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) (b)(8)(iv) Direct observation of performance of instrument maintenance and function checks; This STANDARD is not met as evidenced by: . Based on record review and interviews with testing personnel #1, the laboratory failed to include the direct obeservation of performance of instrument maintenance and function checks in its testing personnel competency assessments for two (October 2023 to October 2025) of two years reviewed. Findings include: 1. A review of the laboratory's competency assessments of its 26 testing personnel between October 2023 and October 2025 revealed a lack of direct obeservation of performance of instrument maintenance and function checks for its white blood cell and it's chemistry panel. 2. A review of the laboratory's "Chem8 i-STAT Device" policy revealed there is an electronic simulator function check to be performed each date of patient testing. 3. An interview on 10/27/25 at 10:10 am with testing personnel #1 revealed the Hemocue white blood cell analyzer has a weekly alcohol cleaning and confirmed competency assessments lacked direct obeservation of performance of instrument maintenance and function checks.